

In the United States Patent and Trademark Office

Serial Number: _____
Appn. Filed: 09/20/03
Applicant(s): DALLAS L CLOUATRE / JAMES M DUNN
Appn. Title: (-)-Hydroxybutyric Acid for Delaying Gastric Emptying
Examiner/GAU: _____
Mailed: 09/20/03
At: SANTA MONICA, CA

Information Disclosure Statement

Assistant Commissioner for Patents
Washington, District of Columbia 20231

Sir:

Attached is a completed Form PTO-1449 and copies of the pertinent parts of the references cited thereon. Following are comments on any non-English language references pursuant to Rule 98:

Very respectfully,

Applicant(s):

Dallas L Clouatre
& James M. Dunn M.D.

Enc.: PTO-1449 & References

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Date: ²⁰⁰³ 09/20/03

LIST OF PRIOR ART CITED BY APPLICANT

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Dallas L. Clouatre, et al.

(-)-HYDROXYCITRIC ACID FOR DELAYING GASTRIC EMPTYING

September 20, 2003

U.S. PATENT DOCUMENTS

		5,945,107	08/1999	Hessel et al.	424	195.1	
		6,160,172	12/2000	Balasubramanyam et al.	562	584	
		6,207,714	03/2001	Clouatre et al.	514	574	
		6,221,901	04/2001	Shrivastava et al.	514	458	
		6,395,296	05/2002	Balasubramanyam et al.	424	439	
		6,447,807	09/2002	Clouatre et al.	424	494	
		6,474,071	11/2002	Clouatre et al.	514	557	
		10/303,117	11/2002	Clouatre, et al.			
		10/447,992	05/2003	Clouatre, et al.			
		2003/ 0119913	06/2003	Ohia et al.	514	574	
		10/616321	07/2003	Clouatre et al.			

OTHER PRIOR ART

Acalovschi M, Dumitrascu DL, Csakany I. Gastric and gall bladder emptying of a mixed meal are not coordinated in liver cirrhosis--a simultaneous sonographic study. *Gut*. 1997 Mar;40(3):412-7.

Andersen T, Fogh J. Weight loss and delayed gastric emptying following a South American herbal preparation in overweight patients. *J Hum Nutr Diet*. 2001 Jun;14(3):243-50.

Aprile LR, Meneghelli UG, Martinelli AL, Monteiro CR. Gastric motility in patients with presinusoidal portal hypertension. *Am J Gastroenterol*. 2002 Dec;97(12):3038-44.

Barrachina MD, Martinez V, Wang L, Wei JY, Tache Y. Synergistic interaction between leptin and cholecystinin to reduce short-term food intake in lean mice. *Proc Natl Acad Sci U S A*. 1997 Sep 16;94(19):10455-60.

FORM PTO-1449 (Substitute)				ATTY. DOCKET NO.		SERIAL NO.	
LIST OF PRIOR ART CITED BY APPLICANT <i>(Use several sheets if necessary)</i>				APPLICANT			
				Clouatre et al.			
				FILING DATE		GROUP	
				September 20, 2003			
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	3,764,692	10/1973	Lowenstein	424	279	
	AB	3,767,678	10/1973	Guthrie et al.	260	343.6	
	AC	3,919,254	11/1975	Guthrie et al.	260	343.6	
	AD	3,993,668	11/1976	Guthrie et al.	260	343.6	
	AE	4,312,885	01/1982	Guthrie et al.	424	317	
	AF	4,443,619	04/1984	Guthrie et al.	549	518	
	AG	5,536,516	07/1996	Moffett et al.	426	271	
	AH	5,626,849	05/1997	Hastings et al.	424	195.1	
	AI	5,656,314	08/1997	Moffett et al.	424	271	
	AJ	5,783,603	07/1998	Majeed et al.	514	574	
	AK	5,914,326	06/1999	McCarty et al.	514	188	
FOREIGN PATENT DOCUMENTS							
	AL	WO 02/14477 A2	02/2002	Majeed et al.			
	AM	WO 03/053454	07/2003	Bagchi et al.			
	AN						
	AO						
	AP						
OTHER PRIOR ART <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
	AR	see attached sheets for additional prior art					
	AS						
	AT						
EXAMINER				DATE CONSIDERED			
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

LIST OF PRIOR ART CITED BY APPLICANT

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Clouatre, et al.

(-)-HYDROXYCITRIC ACID FOR DELAYING GASTRIC EMPTYING

Borovicka J, Schwizer W, Guttman G, Hartmann D, Kosinski M, Wastiel C, Bischof-Delaloye A, Fried M. Role of lipase in the regulation of postprandial gastric acid secretion and emptying of fat in humans: a study with orlistat, a highly specific lipase inhibitor. *Gut*. 2000 Jun;46(6):774-81.

Chaw CS, Yazaki E, Evans DF. The effect of pH change on the gastric emptying of liquids measured by electrical impedance tomography and pH-sensitive radiotelemetry capsule. *Int J Pharm*. 2001 Oct 4;227(1-2):167-75.

Chey WD. Tegaserod and other serotonergic agents: what is the evidence? *Rev Gastroenterol Disord*. 2003;3 Suppl 2:S35-40.

Chial HJ, Camilleri M, Burton D, Thomforde G, Olden KW, Stephens D. Selective effects of serotonergic psychoactive agents on gastrointestinal functions in health. *Am J Physiol Gastrointest Liver Physiol*. 2003 Jan;284(1):G130-7.

Clouatre D, Rosenbaum ME. *The Diet and Health Benefits of HCA (Hydroxycitric Acid)*, 1994.

Debrececi A, Abdel-Salam OM, Figler M, Juricskay I, Szolcsanyi J, Mozsik G. Capsaicin increases gastric emptying rate in healthy human subjects measured by ¹³C-labeled octanoic acid breath test. *J Physiol Paris*. 1999 Nov;93(5):455-60.

Delgado-Aros S, Vella A, Camilleri M, Low PA, Burton DD, Thomforde GM, Stephens D. Effects of glucagon-like peptide-1 and feeding on gastric volumes in diabetes mellitus with cardio-vagal dysfunction. *Neurogastroenterol Motil*. 2003 Aug;15(4):435-43.

Drury, Heber. "Garcinia cambogia" in *The Useful Plants Of India*, 2nd Edition. (William H. Allen and Co., London: 1873) p. 220.

Frost GS, Brynes AE, Dhillon WS, Bloom SR, McBurney MI. The effects of fiber enrichment of pasta and fat content on gastric emptying, GLP-1, glucose, and insulin responses to a meal. *Eur J Clin Nutr*. 2003 Feb;57(2):293-8.

Greenwood MR, Cleary MP, Gruen R, Blase D, Stern JS, Triscari J, Sullivan AC. Effect of (-)-hydroxycitrate on development of obesity in the Zucker obese rat. *Am J Physiol*. 1981 Jan;240(1):E72-8.

LIST OF PRIOR ART CITED BY APPLICANT

Sheet 4 of 7

Clouatre, et al.

(-)-HYDROXYCITRIC ACID FOR DELAYING GASTRIC EMPTYING

Hansen L, Holst JJ. The effects of duodenal peptides on glucagon-like peptide-1 secretion from the ileum. A duodeno--ileal loop? *Regul Pept.* 2002 Dec 31;110(1):39-45.

Hayamizu K, Hirakawa H, Oikawa D, Nakanishi T, Takagi T, Tachibana T, Furuse M. Effect of *Garcinia cambogia* extract on serum leptin and insulin in mice. *Fitoterapia.* 2003 Apr;74(3):267-73.

Hellstrom PM, Naslund E. Interactions between gastric emptying and satiety, with special reference to glucagon-like peptide-1. *Physiol Behav.* 2001 Nov-Dec;74(4-5):735-41.

Heymsfield SB, Allison DB, Vasselli JR, Pietrobelli A, Greenfield D, Nunez C. *Garcinia cambogia* (hydroxycitric acid) as a potential antiobesity agent: a randomized controlled trial. *JAMA.* 1998;280:1596-1600; .; also, especially, *Letters, JAMA* 1999;282:235..

Ishihara K, Oyaizu S, Onuki K, Lim K, Fushiki T. Chronic (-)-hydroxycitrate administration spares carbohydrate utilization and promotes lipid oxidation during exercise in mice. *J Nutr.* 2000 Dec;130(12):2990-5.

Jena BS, Jayaprakasha GK, Singh RP, Sakariah KK. Chemistry and biochemistry of (-)-hydroxycitric acid from *Garcinia*. *J Agric Food Chem.* 2002 Jan 2;50(1):10-22.

Kaplan JM, Siemers WH, Smedh U, Schwartz GJ, Grill HJ. Gastric branch vagotomy and gastric emptying during and after intragastric infusion of glucose. *Am J Physiol.* 1997 Nov;273(5 Pt 2):R1786-92.

Layer P, von der Ohe MR, Holst JJ, Jansen JB, Grandt D, Holtmann G, Goebell H. Altered postprandial motility in chronic pancreatitis: role of malabsorption. *Gastroenterology.* 1997 May;112(5):1624-34.

Leonhardt M, Langhans W. Effect of hydroxycitrate on food intake and body weight regain in rats after hepatic branch vagotomy or sham vagotomy. *Society for the Study of Ingestive Behavior, Annual Meeting* 2001.

Leonhardt M, Langhans W. Hydroxycitrate has long-term effects on feeding behavior, body weight regain and metabolism after body weight loss in male rats. *J Nutr.* 2002 Jul;132(7):1977-82.

Lewis, YS, Neelakantan S. (-)-Hydroxycitric acid--the principal acid in the fruits of *Garcinia cambogia* Desr. *Phytochemistry* 1965;4:619-625.

LIST OF PRIOR ART CITED BY APPLICANT

Sheet 5 of 7

Clouatre, et al.

(-)-HYDROXYCITRIC ACID FOR DELAYING GASTRIC EMPTYING

Lewis YS. Isolation and properties of hydroxycitric acid. In John M. Lowenstein, ed., volume 13 in *Methods in Enzymology, Citric Acid Cycle* (New York: Academic Press, 1969) 613-619.

Loe Y, Bergeron N, et al. Time Course of Hydroxycitrate Clearance in Fasting and Fed Humans. *FASEB Journal* 15;4:632, Abs. 501.1, 2001.

Loe YC, Bergeron N, et al. Gas chromatography/mass spectrometry method to quantify blood hydroxycitrate concentration. *Anal Biochem.* 2001 May 1;292(1):148-54.

Mahendran P, Vanisree AJ, Shyamala Devi CS. The antiulcer activity of *Garcinia cambogia* extract against indomethacin-induced gastric ulcer in rats. *Phytother Res.* 2002 Feb;16(1):80-3.

Matsuda H, Shimoda H, Ninomiya K, Yoshikawa M. Inhibitory mechanism of costunolide, a sesquiterpene lactone isolated from *Laurus nobilis*, on blood-ethanol elevation in rats: involvement of inhibition of gastric emptying and increase in gastric juice secretion. *Alcohol* 2002 Mar-Apr;37(2):121-7.

Matsuda H, Li Y, Yoshikawa M. Roles of capsaicin-sensitive sensory nerves, endogenous nitric oxide, sulfhydryls, and prostaglandins in gastroprotection by momordin Ic, an oleanolic acid oligoglycoside, on ethanol-induced gastric mucosal lesions in rats. *Life Sci.* 1999;65(2):PL27-32.

Matsuda H, Li Y, Murakami T, Yamahara J, Yoshikawa M. Structure-related inhibitory activity of oleanolic acid glycosides on gastric emptying in mice. *Bioorg Med Chem.* 1999 Feb;7(2):323-7.

Matsuda H, Li Y, Yamahara J, Yoshikawa M. Inhibition of gastric emptying by triterpene saponin, momordin Ic, in mice: roles of blood glucose, capsaicin-sensitive sensory nerves, and central nervous system. *J Pharmacol Exp Ther.* 1999 May;289(2):729-34.

Matsuda H, Murakami T, Li Y, Yamahara J, Yoshikawa M. Mode of action of escins Ia and IIa and E,Z-senegin II on glucose absorption in gastrointestinal tract. *Bioorg Med Chem.* 1998 Jul;6(7):1019-23.

Mattes RD, Bormann L. Effects of (-)-hydroxycitric acid on appetitive variables. *Physiol Behav.* 2000 Oct 1;71(1-2):87-94.

Meier JJ, Gallwitz B, Schmidt WE, Nauck MA. Glucagon-like peptide 1 as a regulator of food intake and body weight: therapeutic perspectives. *Eur J Pharmacol.* 2002 Apr 12;440(2-3):269-79.

LIST OF PRIOR ART CITED BY APPLICANT

Sheet 6 of 7

Clouatre, et al.

(-)-HYDROXYCITRIC ACID FOR DELAYING GASTRIC EMPTYING

Nauck MA, Niedereichholz U, Ettler R, Holst JJ, Orskov C, Ritzel R, Schmiegel WH. Glucagon-like peptide 1 inhibition of gastric emptying outweighs its insulinotropic effects in healthy humans. *Am J Physiol.* 1997 Nov;273(5 Pt 1):E981-8.

Ohia SE, Opere CA, LeDay AM, Bagchi M, Bagchi D, Stohs SJ. Safety and mechanism of appetite suppression by a novel hydroxycitric acid extract (HCA-SX). *Mol Cell Biochem.* 2002 Sep;238(1-2):89-103.

Publications & Information Directorate, Council of Scientific & Industrial Research. The Useful Plants of India. (New Delhi: Publications & Information Directorate, 1986) 229.

Rao RN, Sakariah KK. Lipid-lowering and antiobesity effect of (-)-hydroxycitric acid. *Nutrition Research* 1988;8(2):209-212.

Shiotani A, Saeed A, Yamaoka Y, Osato MS, Klein PD, Graham DY. Citric acid-enhanced *Helicobacter pylori* urease activity in vivo is unrelated to gastric emptying. *Aliment Pharmacol Ther.* 2001 Nov;15(11):1763-7.

Singh A, Gull H, Singh RJ. Clinical significance of rapid (accelerated) gastric emptying. *Clin Nucl Med.* 2003 Aug;28(8):658-62.

Sugden MC, et al. Brown-adipose-tissue lipogenesis in starvation effects of insulin and (-)-hydroxycitrate. *Bioscience Reports* 1982;2(5):289-297.

Sullivan C, Triscari J. Possible interrelationship between metabolite flux and appetite. In D. Novin, W. Wyriwicka and G. Bray, eds., *Hunger: Basic Mechanisms and Clinical Implications* (New York: Raven Press, 1976) 115-125.

Sullivan C, Triscari J. Metabolic regulation as a control for lipid disorders. I. Influence of (-)-hydroxycitrate on experimentally induced obesity in the rodent. *Am J Clin Nutr.* 1977 May;30(5):767-76.

Sullivan C, Triscari J. Novel pharmacological approaches to the treatment of obesity. In George A. Bray, ed., *Recent Advances in Obesity Research: II* (Westport, CT: Technomic Publishing Co., 1977) 442-452.

Sullivan AC, Dairman W, Triscari J. (-)-threo-Chlorocitric acid: a novel anorectic agent. *Pharmacol Biochem Behav.* 1981 Aug;15(2):303-10.

LIST OF PRIOR ART CITED BY APPLICANT

Sheet 7 of 7

Clouatre, et al.

(-)-HYDROXYCITRIC ACID FOR DELAYING GASTRIC EMPTYING

Sullivan, A.C., J. Triscari and L. Cheng. Appetite regulation by drugs and endogenous substances. In Myron Winick, ed., *Nutrition and Drugs* (New York: Wiley & Sons, 1983), 139-167. Also published as Sullivan AC, Triscari J, Cheng L. Appetite regulation by drugs and endogenous substances. *Curr Concepts Nutr.* 1983;12:139-67.

Sullivan, Ann C. and J. Triscari. Pharmacologic approaches to the regulation of metabolism and obesity. In Jules Hirsch and Theodore B. Van Itallie, eds., *Recent Advances in Obesity Research: IV* (London: John Libbey, 1983) 196-207.

Sullivan AC, Gruen RK. Mechanisms of appetite modulation by drugs. *Fed Proc.* 1985 Jan;44(1 Pt 1):139-44.

Triscari J, Sullivan AC. Comparative effects of (-)-hydroxycitrate and (+)-*allo*-hydroxycitrate on acetyl CoA carboxylase and fatty acid and cholesterol synthesis *in vivo*. *Lipids* April 1977;12(4): 357-363.

Triscari J, Sullivan AC. Studies on the mechanism of action of a novel anorectic agent, (--) -threo-chlorocitric acid. *Pharmacol Biochem Behav.* 1981 Aug;15(2):311-8.

Tucek S, Dolezal V, Sullivan AC. Inhibition of the synthesis of acetylcholine in rat brain slices by (-)-hydroxycitrate and citrate. *J Neurochem.* 1981 Apr;36(4):1331-7.

Vrang N, Phifer CB, Corkern MM, Berthoud HR. Gastric distension induces c-Fos in medullary GLP-1/2-containing neurons. *Am J Physiol Regul Integr Comp Physiol.* 2003 Aug;285(2):R470-8. Epub 2003 Apr 24.

Westerterp-Plantenga MS, Kovacs EM. The effect of (-)-hydroxycitrate on energy intake and satiety in overweight humans. *Int J Obes Relat Metab Disord.* 2002 Jun;26(6):870-2.

Yoshikawa M, Murakami T, Kishi A, Kageura T, Matsuda H. Medicinal flowers. III. Marigold. (1): hypoglycemic, gastric emptying inhibitory, and gastroprotective principles and new oleanane-type triterpene oligoglycosides, calendasaponins A, B, C, and D, from Egyptian *Calendula officinalis*. *Chem Pharm Bull (Tokyo).* 2001 Jul;49(7):863-70.

Yuan CS, Attele AS, Dey L, Xie JT. Gastric effects of cholecystokinin and its interaction with leptin on brainstem neuronal activity in neonatal rats. *J Pharmacol Exp Ther.* 2000 Oct;295(1):177-82.